

## Initial development of a patient-reported instrument assessing harm, efficacy, and misuse of long-term opioid therapy

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**Abstract**—Guidelines on long-term opioid therapy recommend frequent reassessment of harm, efficacy, and misuse of these potentially harmful and sometimes ineffective medications. In primary care, there is a need for a brief, patient-reported instrument. This report details the initial steps in the development of such an instrument. An interdisciplinary team of clinician-scientists performed four discrete steps in this study: (1) conceptualization of the purpose and function of the instrument, (2) assembly of an item pool, (3) expert rating on which items were most important to include in the instrument, and (4) modification of expert-selected items based on a reading level check and cognitive interviews with patients. A diverse panel of 47 subject matter experts was presented with 69 items to rate on a 1–9 scale in terms of importance for inclusion in the instrument. The panel highly rated 37 items: 8 related to harm, 4 related to efficacy, and 25 related to misuse. These 37 items were then tested for patient comprehension and modified as needed. Next steps in development will include further item reduction, testing against a gold standard, and assessment of the instrument's effect on clinical outcomes.

**Key words:** chronic pain, efficacy, harm, instrument development, misuse, opioid analgesics, opioid therapy, pain management, patient reported, therapeutic monitoring.

### INTRODUCTION

Patients and providers face complex challenges when managing long-term opioid analgesic therapy for

chronic pain. Only a minority of patients may experience benefits from long-term opioid therapy [1–2], and this likelihood must be balanced against potential undesired outcomes, including safety issues ranging from mild toxicities to overdose and death [3] and misuse of these potent medications. To help patients and providers optimize outcomes and mitigate risks, experts advise a strategy of frequent reassessment of harm, efficacy, and misuse in patients on opioids to inform treatment decisions [4–5]. Assessment of harm, efficacy, and misuse of ongoing opioid therapy can be achieved through patient report, e.g., querying patients about side effects and therapeutic effects, and other methods, such as performing urine drug testing to assess for use of unprescribed substances [6] or querying a prescription monitoring database for evidence of multiple prescribers [7]. While the latter strategies are generally recommended and may be useful in the categories of harm and misuse, systematic assessment of patient-reported symptoms, emphasizing those that matter to

**Abbreviations:** IMMPACT = Initiative on Methods, Measurement and Pain Assessment in Clinical Trials; PRIOR = Patient-Reported Indications for Opioid Reassessment; VA = Department of Veterans Affairs; VHA = Veterans Health Administration.

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patients, has been recognized as a critical and often overlooked piece of high-quality medication management in general [8–9] and of ongoing opioid therapy in particular [4,10].

Experts have identified the phenomenon of clinical inertia—not making a change in therapy that may be indicated—as one of the factors driving the ongoing unprecedented rates of opioid prescribing [11–12]. Furthermore, there are emerging qualitative data from patients and providers about a troubling disconnect: the patient continues the therapy because the prescriber continues writing the prescriptions (not because the medication is effective) and the prescriber continues to write the prescriptions because of the untested assumption that the patient is satisfied with the treatment [13–14]. These findings drive our hypothesis that a brief instrument, protocolized into routine follow-up, may promote a more active surveillance approach and combat clinical inertia.

However, to date, there is no widely accepted, validated, patient-reported instrument available to monitor the harm, efficacy, and misuse of opioid therapy prescribed for patients with chronic pain. A recent systematic review identified nine published instruments that assessed at least one of these categories, none of which had been tested in clinical practice [15]. This shortcoming contributed to the conclusion that none of these instruments were comprehensive and feasible to implement in clinical practice. In light of this identified gap, our long-term goal is to develop such an instrument. The purpose of the present study was to describe the methods used to develop the preliminary version of an instrument designed to measure patient-reported harm, efficacy, and misuse of opioid therapy that will ultimately undergo further testing.

## METHODS

### Overview of Study Design

We performed four discrete steps in this study: (1) conceptualization of the purpose and function of the instrument, (2) assembly of an item pool, (3) expert rating of items from the pool most important to include in the preliminary version, and (4) modification of expert-selected items based on a reading level check and cognitive interviews with patients. Each component of the study was approved by the Department of Veterans Affairs (VA) Connecticut Healthcare System Human Subjects Subcommittee

and the Yale University School of Medicine's Institutional Review Board.

### Purpose and Function of Instrument

We convened a core research team, composed of clinician researchers with diverse training and experience in primary care/internal medicine, rheumatology, psychology, pain medicine, addiction medicine, nursing, psychometrics, and clinical epidemiology, to discuss the identified gap in opioid monitoring and establish the purpose and function of a new instrument. Consensus emerged that the instrument should be (1) developed for use in primary care, where most long-term opioid therapy is prescribed; (2) patient-reported and patient self-administered in order to improve efficiency and eliminate barriers to completion; (3) designed to be sensitive to incipient or developing harms and low or absent benefit; (4) complementary to existing measures of pain and opioid misuse; and (5) designed such that one or more positive responses to items on the instrument would prompt a more detailed clinical assessment of each positive response. As such, there would be no scaling or scoring of the instrument. We plan to name the final instrument the Patient-Reported Indications for Opioid Reassessment (PRIOR).

### Assembly of Item Pool

We first performed a systematic review to identify instruments containing patient self-reported items related to safety, efficacy, and misuse of opioid therapy [15] and sorted items from these instruments ( $n = 9$ ) by category (safety, efficacy, misuse, or other). The core research team reached consensus on whether this pool lacked any important items by comparing the list of efficacy-related items to the Initiative on Methods, Measurement and Pain Assessment in Clinical Trials (IMMPACT) recommended domains for assessing analgesic efficacy in clinical trials [16] and comparing the list of harm-related items with a literature search of opioid-related harms. Beyond these two sources, a suitable item was identified from the broader medical literature for any specific content area identified as missing.

### Eliminating Items

First, we removed items that did not directly pertain to harm, efficacy, or misuse of current opioid therapy. Next, we identified items with identical or near-identical syntax and removed those items judged to have less clear syntax. We then removed items that were not written in patient-reported format if the item's content was covered

by a similar, patient-reported item. Since interpreting the clinical significance of single time point numeric ratings can be challenging [17], we removed items relying on numeric scales in the response if similar items not requiring use of a numeric rating scale were available. Finally, in recognition that three of the instruments identified in the systematic review were designed for clinical research on opioid-induced constipation (the Bowel Function Index, the Patient Assessment of Constipation Symptoms, and the Bowel Function Diary) and contained a level of detail on constipation unnecessary for primary care-based screening, we chose three items that adequately covered the concept of opioid-induced constipation rather than including all the constipation-related items.

### Item Modification and Standardization

If a single item contained more than one content area, we revised it to create multiple items covering each one. For items not written in patient-reported format and if the content was not otherwise covered in one of the remaining items, we modified them into patient-reported format based on examples from the broader medical literature. To promote ease of evaluation by the expert panel and, ultimately, use of the instrument in clinical practice, we standardized the items in three ways. First, we edited each item to include a common stem, “In the last 30 days . . .” to fit the planned use of the instrument multiple times per year. With our goal of developing an instrument sensitive to harm-related problems, asking a patient to evaluate a symptom and additionally whether that symptom was related to or caused by opioids seemed unnecessarily complex and a potential source of low sensitivity. Therefore, when possible, we removed attribution of symptoms to opioids from items when such attribution was asked of the patient. If attribution was the crux of the question (e.g., “Have you been bothered by side effects of opioid pain medications?”), we did not modify the item. Last, we transformed each item into a question with a yes/no response, whereby the “yes” response would denote an issue of clinical significance requiring more detailed assessment.

### Subject Matter Expert Item Rating

A priori, we defined a subject matter expert as someone who (1) believes that, at least in some instances, opioids can be safely and effectively used for the treatment of chronic noncancer pain; (2) prescribes and manages

opioids for chronic noncancer pain; and (3) has an established clinical or research interest in chronic pain management. We used two sources to identify potential subject matter experts: (1) the Veterans Health Administration (VHA) pain points of contact list, consisting of pain-interested clinicians responsible for dissemination and implementation of VHA pain-related policies at each VHA facility nationally ( $n = 108$ ), and (2) the VHA pain research working group listserv, whose membership consists of VHA pain-relevant investigators ( $n = 30$ ).

As is increasingly common, our expert item-rating process used an Internet-based survey platform (Qualtrics; Provo, Utah). We sent an email message to potential participants in which we provided a description of the project, noted the voluntary nature of participation, and embedded a link to the Web-based survey. In the survey, there were two screening questions regarding opioid therapy for chronic noncancer pain and a short demographics section. After describing the purpose of the instrument, we presented the participants with 69 items, sorted by category (harm, efficacy, or misuse), and asked them to rate each item on a 1–9 scale with respect to its importance for inclusion in the instrument (1 = not important, 9 = very important), based on the stated purpose of the instrument. Participants were asked to write in any items not listed that they believed should be included. Adapted from a published methodology [18], we identified the highly rated items using prespecified criteria: median response value of 8 or 9 with agreement, defined as 70 percent of values of 7, 8, or 9. We stipulated a priori that at least two items from each category would need to be present in the preliminary version of the instrument, even if they did not meet the definition of highly rated. We planned for the option of a second round of rating if there were new items suggested by subject matter experts or the absence of agreement on highly rated items.

### Reading Level Check and Cognitive Interviews with Patients

An important step in the development of a patient-reported instrument, especially one that will be self-administered, is verifying that patients understand what the items mean [19]. To improve the comprehensibility of the items, we undertook two additional steps with the highly rated items: assessing the reading level of the items and performing cognitive interviews with patients on opioids. The reading level of each item was assessed using the Fog Index [20], which uses a scoring system of

reading level based on the numbers of words per sentence and the number of polysyllabic words per paragraph. Next, we performed cognitive interviews with patients in which, in 1:1 sessions, each patient was asked to read each item out loud and interpret, in his or her own words, what each item was asking. This “think aloud” procedure has been used in developing other patient-reported instruments [21]. Modifications were made for any item for which there was recurrent confusion. We conducted interviews until the most recent version was accurately interpreted by 10 consecutive participants.

## RESULTS

### Assembly of Item Pool

The **Figure** displays how the 129 items identified in the systematic review were reduced to the 69 items presented to the expert panel. Based on comparison to the domains recommended by IMMPACT, no items identified in the systematic review covered the specific efficacy-related content areas “functional interference” and “emotional interference.” Therefore, we added one item each from the National Institutes of Health’s Patient-Reported Outcomes Information System item bank related to these specific content areas [22]. Our literature review of opioid-related harms revealed two adverse outcomes—falls [23] and motor vehicle accidents [24]—not accounted for in the item pool; thus, we added an item about each [25–26].

### Eliminating Items

The largest group of eliminated items were not written in patient-reported format but contained content covered elsewhere ( $n = 24$ ). As mentioned previously, for parsimony while at the same time attempting to cover this common side effect, we retained three items related to constipation: “Have you been bothered by constipation?,” “Have you been bothered by hard stools?,” and “Have you been bothered by straining or squeezing to try to pass bowel movements?,” and removed the rest ( $n = 20$ ). The next largest group of eliminated items ( $n = 14$ ) was judged as not directly pertaining to harm, efficacy, and misuse of current opioid therapy. Several of these items were historical in nature, e.g., “Have you ever had a drug or alcohol addiction problem?,” and thus not practical for recurring use. Others sought to measure characteristics not directly related to the patient’s own experience of harm, efficacy, or misuse, for example, “Do any of your family members

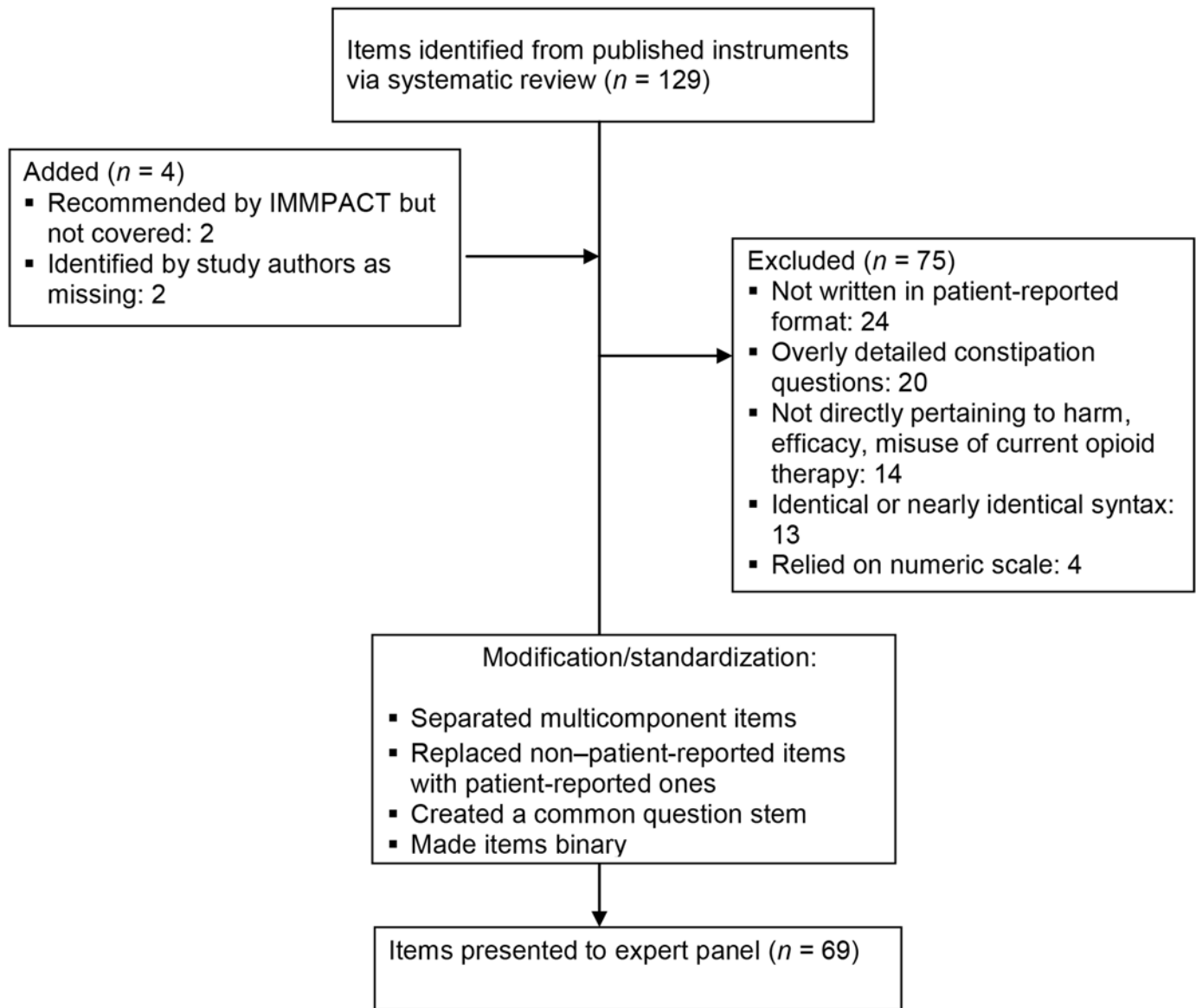
disagree with your use of pain medications?” We eliminated 13 items with identical or nearly identical syntax to another item that was retained. For example, we considered “Is anyone in your family or among your friends concerned that you might be addicted to pain medications?” and “Family or friends have thought that I may be dependent on or addicted to opiate pain medications” nearly identical and eliminated the latter due to ambiguity of the term “dependent on.” Four items relying on numeric scales, e.g., “What percentage of your pain has been relieved during the past week?,” were eliminated.

### Item Modification and Standardization

We divided items containing more than one component into single component items: for example, “I have felt depressed, down, or anxious” became “I have felt depressed,” “I have felt down,” and “I have felt anxious.” We replaced non-patient-reported items not covered elsewhere with patient-reported versions. For example, the item “Ask patient about vomiting” was replaced by, “Have you been bothered by vomiting?,” gleaned from a patient-reported instrument for gastric dysmotility [27]. Finally, to create binary items where a positive response was clinically meaningful, we inserted “bothered by” to reduce the possibility that the patient would endorse the item based on a clinically trivial level of symptoms, for example, “In the past 30 days, have you been bothered by constipation?” replaced, “In the past 30 days, have you been constipated?”

### Subject Matter Expert Item Rating

The response rate to the survey for potential subject matter experts was 54 percent (75/138). Of the 75 respondents, 29 did not meet subject matter expert criteria (2 did not believe that opioids could be safely and effectively used in the treatment of chronic noncancer pain and 27 did not prescribe and manage opioid therapy for chronic noncancer pain). Of the 47 subject matter experts, 23 were women (49%), half were in the 46 to 55 yr age group, and each of VHA’s 21 geographically contiguous catchment areas was represented. The largest group of subject matter experts was trained in general internal medicine/family medicine/primary care ( $n = 19$ ), followed by pain/anesthesiology ( $n = 15$ ), with addiction medicine, neurology, nursing, physiatry/physical medicine and rehabilitation, psychiatry, and rheumatology also represented. The expert panel highly rated 37 of the 69 items based on the criteria described; see [Appendix 1](#) (available online only) for complete results of the item

**Figure.**

Item pool development. IMMPACT = Initiative on Methods, Measurement and Pain Assessment in Clinical Trials.

rating process. Of the 37 highly rated items, 8 were related to harm, 4 were related to efficacy, and 25 were related to misuse. The median response value of each included harm-related item was 8, except “Have you felt sleepy or less alert when driving or operating machinery?,” which had a median response value of 9. Since there was consensus on highly rated items and there were no new patient-reported items suggested by the expert panel, a second round of rating was not necessary.

In anticipation of further testing of the PRIOR in future studies, we consulted with the lead authors of the original instruments for permission to use their items. All but two authors granted permission, which affected two of the 37 items. For both items, we selected the next highest-rated item that was similar in content.

**Reading Level Check and Cognitive Interviews**

The reading level check did not lead to any item modifications because we had already shortened long

items in a previous step by breaking down multicomponent single items into multiple single-component items. Additionally, there was a low density of polysyllabic words. There was, however, heterogeneity among the items in how opioids were referred to and also whether the term “physician” or “doctor” was used. Based on the cognitive interviewing process, we identified “opioid pain medication” and “doctor” as the universally understood versions of these terms. Additionally, in the cognitive interviewing process, we learned that several patients thought the word “sedated” meant “knocked out” or “unconscious”; therefore, we changed this term to “overly drowsy” in keeping with other studies of centrally acting, sedating medications [28]. Following our *a priori* established protocol, the cognitive interviewing process was complete when 10 consecutive subjects interpreted all the items in the same way without confusion, which occurred after 16 interviews. The preliminary version of the PRIOR is contained in [Appendix 2](#) (available online only).

## DISCUSSION

Through a multistep process, we developed a preliminary version of the PRIOR, a patient-reported instrument for identifying opioid harm, low efficacy, and misuse among patients on long-term opioids. The PRIOR is designed to fill a gap based on systematic review of the literature; accordingly, we aimed for it to be comprehensive, covering harm, efficacy, and misuse; to be patient-reported and patient self-administered in order to improve efficiency and eliminate barriers to completion, especially in primary care; and to yield clinically actionable information. Consistent with our goal of comprehensiveness, the subject matter expert panel in the present study highly rated at least four items from each of the harm, efficacy, and misuse categories. This spread of items across categories, while to some degree enforced by design, reflects the expert panel’s interest in not just assessing traditionally provider-centered concerns (i.e., misuse), but also patient-centered ones (e.g., harm and efficacy). Feasibility is yet to be established. However, at 37 items, especially the 25 items related to misuse, this preliminary instrument is too long and will require further item reduction to be used in busy primary care practices. While several design decisions should promote the clinical utility of the PRIOR, this will ultimately be

determined by field testing of a briefer version in subsequent studies.

The strengths of this work include, first, the rigorous approach to understanding the current needs in opioid monitoring through systematic review and also gathering input from a diverse research team with broad expertise. Second, the process for item selection brought together a large, diverse group of subject matter experts who efficiently arrived at consensus. Finally, the standardization of items and use of cognitive interviewing to ensure patient comprehension were critical steps often lacking in other instrument development processes.

A number of decisions in the design of the preliminary PRIOR deserve further discussion. The first is our decision to disaggregate previously validated multi-item instruments into their component items for voting by the expert panel. We considered this consistent with our overall conceptualization of the final PRIOR as a checklist of symptoms and behaviors in which each item would have its own inherent meaning and, if positive, would indicate the need for further clinical assessment. Additionally, the use of items from previously validated instruments afforded the advantage that each item had already been tested to some degree for patient comprehension or other validity. The next decision was to include only VHA clinicians in the expert panel. In recognition of the fact that VHA routinely uses other related instruments in clinical settings (e.g., the pain numerical rating scale, Patient Health Questionnaire-2 for depression), we are designing the PRIOR for use in VHA and thus wanted input from experts who work in the VHA system. Finally, we included nurse practitioners and physician assistants in the expert panel since these clinicians function as primary care providers in the VHA system and thus can contribute the same breadth of experience and expertise to this process.

The current study has limitations. First, while disaggregating other instruments may ultimately contribute to a brief, feasible instrument, it is possible that accuracy may be compromised if certain symptoms or behaviors are better assessed with intact groups of items. We consider this an acceptable trade-off of maximizing feasibility and sensitivity but sacrificing some specificity, which can be gained by the ensuing patient-provider discussion. Second, patient self-report of misuse may be inaccurate, especially when doing so may threaten future prescriptions [29], and yet over half of the preliminary PRIOR is misuse-related. We expect that in future development

steps, the number of misuse-related items will be reduced markedly; it may ultimately be determined that only one or two misuse-related items are worthwhile for use in a patient-reported instrument and that the bulk of the relevant data would come from non-patient-reported assessments such as urine drug tests, pill counts, and querying a prescription monitoring database.

## CONCLUSIONS

As mentioned previously, next steps in this work include item reduction and field testing. To achieve that aim along with examining the psychometric properties of the instrument, we plan additional data collection and instrument analysis using Rasch methodology [30]. Patients taking opioids will self-administer the preliminary PRIOR as part of usual clinical care. Rasch analysis uses these data to create a hierarchy of the items on a unidimensional spectrum of difficulty, allowing elimination of misfitting and overcorrelated items and providing evidence for reliability and validity. Through this process, patient input will be incorporated since items that are never or very rarely endorsed will be dropped. The goal is to develop a briefer instrument with minimal respondent burden, which we will then compare against a standardized in-depth clinical assessment, including corollary non-patient-reported measures (e.g., urine drug testing and querying a prescription monitoring database), and finally test in clinical practice for its effect on harm, efficacy, and misuse-related outcomes. Our hypothesis is that the PRIOR will add significant value to the current standardized measures of pain intensity (e.g., the pain numerical rating scale) and opioid harm, but this hypothesis should be tested before broad dissemination. This preliminary version of the PRIOR provides a strong foundation for these future efforts.

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### Author Contributions:

*Study concept and design:* W. C. Becker, D. A. Fiellin, A. C. Black, C. T. Kostovich, R. D. Kerns, L. Fraenkel.

*Acquisition of data:* W. C. Becker, R. D. Kerns, L. Fraenkel.

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*Drafting of manuscript:* W. C. Becker, L. Fraenkel.

*Critical revision of manuscript for important intellectual content:*

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